

CHAPTER 2.3.13.

BOVINE SPONGIFORM ENCEPHALOPATHY

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Article 2.3.13.3.

**BSE free country or zone**

The cattle population of a country or zone may be considered free of BSE should the following conditions be met:

- 1) a risk assessment, as described in point 1) of Article 2.3.13.2., has been conducted and it has been demonstrated that appropriate measures have been taken for the relevant period of time to manage any risk identified;
- 2) either:
  - a) there has been no *case* of BSE; and either:
    - i) the criteria in points 2) to 5) of Article 2.3.13.2. have been complied with for at least 7 years; or
    - ii) the criteria in point 3) of Article 2.3.13.2. have been complied with for at least 7 years and it has been demonstrated that for at least 8 years no *meat-and-bone meal* or *greaves* have been fed to ruminants;

OR

- b) all *cases* of BSE have been clearly demonstrated to originate directly from the importation of live cattle, and the affected cattle as well as, if these are females, all their progeny born within 2 years prior to, and after, clinical onset of the disease, if alive in the country or zone, when slaughtered or at death, are completely destroyed, their last progeny born within 2 years prior to, or after, clinical onset of the disease, if alive in the country or zone, have been slaughtered and completely destroyed; and either:
  - i) the criteria in points 2) to 5) of Article 2.3.13.2. have been complied with for at least 7 years; or
  - ii) the criteria in point 3) of Article 2.3.13.2. have been complied with for at least 7 years and it has been demonstrated that for at least 8 years no *meat-and-bone meal* or *greaves* have been fed to ruminants;

OR

- c) the last indigenous *case* of BSE was reported more than 7 years ago,
  - i) the criteria in points 2) to 5) of Article 2.3.13.2. have been complied with for at least 7 years; and
  - ii) the feeding of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants has been banned and the ban has been effectively enforced for at least 8 years; and

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Appendix XI (contd)

iii) the affected cattle as well as:

- = if these are females, all their progeny born within 2 years prior to, and after, clinical onset of the disease, if alive in the country or zone, when slaughtered or at death, are completely destroyed, and
- = all cattle which, during their first year of life, were reared with the affected cattle during their first year of life, and, which investigation showed consumed the same potentially contaminated feed during that period, or
- = where the results of an investigation are inconclusive, all cattle born in the same herd as, and within 12 months of the birth of, the affected cattle,  
if alive in the country or zone, when slaughtered or at death, are completely destroyed.

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Article 2.3.13.8.

Regardless of the BSE status of the *exporting country*, *Veterinary Administrations* should authorise without restriction the import or transit through their territory of the following *commodities*:

- 1) *milk and milk products*
- 2) semen and *in vivo* derived cattle embryos collected and handled in accordance with the recommendations of the International Embryo Transfer Society;
- 3) ~~protein free tallow (maximum level of insoluble impurities of 0.15% in weight) and derivatives made from this tallow;~~
- 4) dicalcium phosphate (with no trace of protein or fat);
- 5) hides and skins;
- 6) gelatin and collagen prepared exclusively from hides and skins.

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Article 2.3.13.21.

*Veterinary Administrations of importing countries* should require:

for tallow (~~other than protein free tallow as defined in Article 2.3.13.8.)~~ intended for food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices

the presentation of an *international veterinary certificate* attesting that it originates from:

- 1) a BSE free or provisionally free country or zone, or
- 2) a country or zone with a minimal BSE risk, and it originates from cattle which have been subjected to an ante-mortem inspection for BSE with favourable results and has not been prepared using the tissues listed in point 3 of Article 2.3.13.19., or

- 3) a country or zone with a moderate BSE risk, and it originates from cattle which have been subjected to an ante-mortem inspection for BSE with favourable results and has not been prepared using the tissues listed in point 2 of Article 2.3.13.19.

Article 2.3.13.22.

*Veterinary Administrations of importing countries* should require:

for tallow derivatives ~~(other than those made from protein-free tallow as defined in Article 2.3.13.8.)~~  
intended for food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices

the presentation of an *international veterinary certificate* attesting that:

- 1) they originate from a BSE free or provisionally free country or zone, or from a country or zone with a minimal BSE risk;

OR

- 2) they have been produced by hydrolysis, saponification or transesterification using high temperature and pressure.

Article 2.3.13.23.

Careful selection of source materials is the best way to ensure maximum safety of ingredients or reagents of bovine origin used in the manufacture of medicinal products.

Countries wishing to import bovine materials for such purposes should therefore consider the following factors:

- 1) the BSE status of the country and herd(s) where the animals have been kept, as determined under the provisions of Articles 2.3.13.2. to 2.3.13.7.;
- 2) the age of the donor animals;
- 3) the tissues required and whether or not they will be pooled samples or derived from a single animal.

Additional factors may be considered in assessing the risk from BSE, including:

- 4) precautions to avoid contamination during collection of tissues;
  - 5) the process to which the material will be subjected during manufacture;
  - 6) the amount of material to be administered;
  - 7) the route of administration.
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